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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/648,056	08/26/2003	Jeff R. Justis	4002-3368/PC753.00	2957
52196	7590	04/05/2006	EXAMINER	
KRIEG DEVAULT LLP ONE INDIANA SQUARE, SUITE 2800 INDIANAPOLIS, IN 46204-2709			STEWART, ALVIN J	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 04/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/648,056

Applicant(s)

JUSTIS ET AL.

Examiner

Alvin J. Stewart

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,5-7,11-14,44-47,51-57 and 60-69 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,5-7,11-14,44-47,51-57 and 60-69 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

Claims 2-4, 8-10, 48-50, 58 and 59 are withdrawn from further consideration.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5, 7, 11, 14, 44, 45, 47, 51, 54-56, 61 and 64-69 are rejected under 35 U.S.C. 102(b) as being anticipated by Baumgartner US Patent 5,755,797.

Baumgartner discloses an intervertebral reduction system comprising a plurality of reduction elements positionable in an intervertebral space adjacent one another, the elements include a spherical shape, an exterior surface and a cavity extending through the reduction element.

*NOTE: regarding claims 1 and 44, the last three lines of claim 1 and the last two lines of claim 44, the Examiner has not given patentable weight to the “thereby” clause because the “thereby” clause merely states the result of the limitations in the claim and adds nothing to the patentability or substance of the claim. See Texas Instruments Inc. v. International Trade Commission, 26 USPQ2d 1010 (Fed. Cir. 1993); Griffin v. Bertina, 62 USPQ2d 1431 (Fed. Cir. 2002); Amazon.com Inc. v. Barnesandnoble.com Inc., 57 Uspq2d 1747 (Fed. Cir. 2001).*

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6, 46 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baumgartner US Patent 5,755,797.

Baumgartner discloses the invention substantially as claimed. however, Baumgartner does not disclose the reduction elements made of PMMA.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the material property of the Baumgartner reference because Applicant has not disclosed that the PMMA material provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the polyethylene material of the Baumgartner reference because the material is capable of absorbing the forces exerted in the body and they are biocompatible.

Therefore, it would have been an obvious matter of design choice to modify the Baumgartner reference to obtain the invention as specified in claims 6 and 46.

Claims 12, 13, 52, 53, 60, 62 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baumgartner US Patent 5,755,797 in view of Trieu US Patent 6,620,196 B1.

Baumgartner discloses the invention substantially as claimed. However, Baumgartner does not disclose a material located in the intervertebral space around the reduction elements.

Trieu teaches an intervertebral implant comprising a reduction element (15) covered by a material placeable (30) in the intervertebral space around the reduction element for the purpose of anchoring the implant to the wall of the vertebral body and avoid the expulsion of the implant from the disc cavity, promote the growth of fibrous tissue and provide mechanical support to the disc (see col. 5, lines 20-67; col. 6, lines 62-67; and col. 7, lines 1-32).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Baumgartner reference with the material placeable in the intervertebral space around the implant in order to anchor the implant to the wall of the vertebral body and avoid the expulsion of the implant from the disc cavity, promote the growth of fibrous tissue and provide mechanical support to the disc.

Regarding claims 13, 53 and 63, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the material property of the Trieu reference because Applicant has not disclosed that the PMMA material provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the plurality of polymeric materials disclosed in the Trieu reference because the material is capable of been bioabsorbable, absorb the forces exerted in the implant and anchor the implant to the disc cavity.

Therefore, it would have been an obvious matter of design choice to modify the Trieu reference to obtain the invention as specified in claims 13, 53 and 63.

#### ***Response to Arguments***

Applicant's arguments filed 09/09/05 have been fully considered but they are not persuasive.

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The Applicant's representative disagrees with the Examiner's point of view. The Applicant's representative discloses that the Baumgartner reference does not disclose the claimed arrangement, relationship and organization of features as recited in the rejected claims. For example, the reference does not disclose a plurality of reduction elements that act one upon the other upon sequential positioning thereof in the intervertebral space thereby compressing cancellous bony tissue and applying an outwardly directed corrective force.

The Examiner disagrees with the Applicant's point of view. The Examiner is looking for structure limitations that can overcome a prior art. The limitations, that the Applicant's representative is arguing, are functional limitations that are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

Regarding claims 1, 44 and 55, the Examiner has not given patentable weight to the "wherein" clause because a "wherein" clause that merely states the result of the limitations in the claim adds nothing to the patentability or substance of the claim. See *Texas Instruments Inc. v. International Trade Commission*, 26 USPQ2d 1010 (Fed. Cir. 1993); *Griffin v. Bertina*, 62 USPQ2d 1431 (Fed. Cir. 2002); *Amazon.com Inc. v. Barnesandnoble.com Inc.*, 57 Uspq2d 1747 (Fed. Cir. 2001).

Regarding the thereby clause see note above.

Finally, the structure limitations discloses in the prior art are capable of disclosing a plurality of reduction elements that act one upon the other upon sequential positioning thereof in the intervertebral space thereby compressing cancellous bony tissue and applying an outwardly directed corrective force.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alvin J Stewart whose telephone number is 703-305-0277. The examiner can normally be reached on Monday-Friday 7:00AM-5:30PM(1 Friday B-week off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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**ALVIN J. STEWART**  
**PRIMARY EXAMINER**

April 2, 2006.